IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION *This relates to: All Actions*	No. 1:19-md-2875-RBK Hon. Robert Kugler Redacted Version

PLAINTIFFS' MEMORANDUM OF LAW IN OPPOSITION TO DEFENDANTS' MOTION TO EXCLUDE THE EXPERT TESTIMONY OF RENA CONTI, PH.D. (ECF 2633)

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page

Cases

TABLE OF AUTHORITIES

Page

TABLE OF AUTHORITIES

Other Authorities

I. INTRODUCTION

At class certification, this Court completely denied Defendants' *Daubert* challenge to Plaintiffs' damages expert, Dr. Rena Conti. *See* ECF 2261. The Court specifically held that "[a]s a PhD in the Economics of Health Policy, Dr. Conti is qualified to opine on economic loss in this litigation." *Id.* at 86. The Court "considered carefully all of the parties' arguments" (*id.* at 87) to find that Dr. Conti reliably applied a generally accepted methodology to establish the fact of damage (e.g., adulterated VCDs are worthless). *Id.* at 88-89. The Court also found Dr. Conti adequately applied a sufficiently reliable methodology to calculate class damages (based in part on gold-standard IQVIA data). *Id.* Indeed, as this Court rightly recognized, the same principal methodology Dr. Conti applies here was found to be reliable by another court in this Circuit in a litigation just like this one that involved worthless, adulterated drugs. *Id.* at 88-89.

Defendants' instant *Daubert* motion, built on an imaginary world in which the contaminated VCDs could have been sold despite their adulteration, and no recalls occurred, is nothing more than a rehash of their same rejected *Daubert* arguments at class certification, plus a dash of their summary judgment arguments awkwardly recast through the *Daubert* prism. No matter. Defendants once again vainly try to wedge their weight- and credibility-based attacks into the Rule 702 rubric of

qualifications, reliability, and fit. But, as before, Defendants' quibbles with Dr. Conti's conclusions or inputs do not implicate the admissibility of her opinions.

First, Dr. Conti is a preeminently credentialed healthcare economist, who has served as an advisor to the U.S. Food and Drug Administration ("FDA") on issues related to generic drug pricing and supplies. Dr. Conti is sufficiently qualified under Rule 702. Defendants do not argue otherwise.

Second, Defendants' reliability arguments as to Dr. Conti's report largely focus on her conclusion (*viz.*, whether adulterated drugs have any economic value or not), and not her methodology. This represents an upheaval of the *Daubert* analysis, is unmoored from the law of this jurisdiction, and is completely without merit. Further, as this Court noted at class certification, it is the factfinder's role to weigh the parties' competing expert opinions on damages.

Third, Defendants' critiques about Dr. Conti's position on Medicare money "offsets" and the reliability of the gold-standard IQVIA data she partly relies on are not true reliability attacks. Defendants' analysis picks isolated facts and fails to acknowledge Dr. Conti's explanation for the price variances in the data sets, seeking to miscast her as having no methodological explanation when in fact she has an on-point reliable explanation. At best, these criticisms go to Rule 702's "sufficient facts or data" prong. In either case, both also lack merit.

Dr. Conti comprehensively and reliably explains why, based on economics and market realities, Medicare monies are not an "offset" that should reduce certain TPP trial subclass members' damages. Medicare monies also are hopelessly speculative and Defendants are clearly barred under applicable law by the collateral source doctrine from attempting to claim credit. Further, proof of offsets or damages reductions are Defendants' burden, not Plaintiffs', and Defendants have utterly failed to present reliable figures.

Defendants' more recent attack on the IQVIA data Dr. Conti uses in her modeling fares even worse. This robust collection of real-world data captures by far the most comprehensive and robust set of drug pricing information available. IQVIA is widely used and accepted by the pharmaceutical industry, academics, courts throughout this Circuit and country, and even Defendants themselves as [redacted] The data is sufficient for purposes of Dr. Conti's opinions. Defendants present a disingenuous overview in their motion, and when the actual facts are evaluated they have identified nothing that so undermines the credibility and accuracy of Dr. Conti's IQVIA-based damages calculations to warrant preclusion. A "reasonable estimate" of damages is sufficient.

Defendants' gotcha questioning based on certain boilerplate disclaimers in the IQVIA data is of no moment. Countless courts, industry participants, academics,

experts (including Defendants' own), and even Defendants themselves routinely rely on IQVIA data. Defendants' contentions also go to weight, not admissibility.

Finally, Defendants' "fit" arguments are nothing but a mishmash of Defendants' infirm summary judgment arguments. Defendants' argument that "point of sale" does not mean "point of sale" is tortured and factually unsupportable. Defendants' assertion that Dr. Conti's damages calculations did not properly or timely break-out numbers by state simply is incorrect.

Defendants' *Daubert* motion (ECF 2633) should be denied.

II. APPLICABLE LEGAL STANDARD

"Under the Federal Rules of Evidence, a trial judge acts as a 'gatekeeper' to ensure that 'any and all expert testimony or evidence is not only relevant, but also reliable.'" *Pineda v. Ford Motor Co.,* 520 F.3d 237, 243 (3d Cir. 2008) (citation omitted). Rule 702, the rule that governs expert testimony, has a "liberal policy of admissibility." *Id.* The expert testimony must meet the following requirements: "(1) the proffered witness must be an expert, i.e., must be qualified; (2) the expert must testify about matters requiring scientific, technical or specialized knowledge; and (3) the expert's testimony must assist the trier of fact." *Id.* at 244. Defendants' protestations to the contrary, the new amendment to Rule 702 merely clarifies the existing standard of expert admissibility, which this Court already applied correctly in evaluating the reliability of Dr. Conti's methodology and calculations. The

amendment does not alter existing law and does not "impose[] any new, specific procedures." Fed. R. Evid. 702, advisory committee's note to 2023 amendment.

A. Qualifications

The qualification requirement of Rule 702 is "liberally construed" and satisfied if an expert "possesses specialized expertise." *Geiss v. Target Corp.*, 2013 WL 4675377, at *4 (D.N.J. 2013) (citing *Pineda,* 520 F.3d at 244).

B. Reliability

The second Rule 702 requirement (also known as reliability) is taken to "mean[] that the expert's opinion must be based on the 'methods and procedures of science' rather than on 'subjective belief or unsupported speculation.'" *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 742 (3d Cir. 1994) (citation omitted). While such "good grounds" for an expert's opinion are required, "[t]he grounds for the expert's opinion merely have to be good, they do not have to be perfect." *Id.* at 744. Good grounds may exist even if the court believes there "are better grounds for some alternative conclusion" or that "a scientist's methodology has some flaws such that if they had been corrected, the scientist would have reached a different result." *Id.*

Moreover, proponents of expert testimony do not have to "demonstrate to the judge by a preponderance of the evidence that the assessments of their experts are *correct*, they only have to demonstrate by a preponderance of evidence that their opinions are reliable." *In re DVI, Inc. Sec. Litig.*, 2014 WL 4634301, at *5 (E.D. Pa.

Sep. 16, 2014) (internal quotation marks omitted) (emphasis original); *see also In re Paoli*, 35 F.3d at 744 ("evidentiary requirement of reliability is lower than the merits standard of correctness"). Scientific study is not the only basis for an expert's reliability, which may also be founded upon experience.

As the Supreme Court later added in *Kumho Tire*, the objective of *Daubert* "is to make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999). Indeed, the *Daubert* test "may be more flexibly applied in cases where the expert testimony is based on experience." *In re Front Loading Washing Mach. Class Action Litig.*, 2013 WL 3466821, at *2 (D.N.J. July 10, 2013). Moreover, in the case of experience-based opinions, the fact that an expert has been determined to be qualified weighs in favor of the reliability of her report. *Altieri v. State Farm Fire & Cas. Co.*, 2011 WL 1883054, at *3 (E.D. Pa. May 17, 2011). In this Circuit, "courts limit the *Daubert* inquiry to expert testimony offered to prove satisfaction of Rule 23's requirements." *In re Blood Reagents Antitrust Litig.*, 783 F.3d 183, 188 n.8 (3d Cir. 2015).

C. Relevance

The third requirement of Rule 702, known as relevance or fit, is satisfied "if an opinion fits a particular case (and thus helps the trier of fact)" – i.e., there must

be a "connection between the scientific research or test result to be presented and particular disputed factual issues in the case." *Geiss*, 2013 WL 4675377, at *5 (internal quotation marks omitted).

III. BACKGROUND ON DR. CONTI'S EXPERT REPORTS

A. Dr. Conti's Qualifications

Defendants diminish Dr. Conti's vast expertise by merely describing her as an "associate professor" and an affiliate of a "consulting and litigation support firm." *See* Defs.' Mem. at 3. In reality, Dr. Conti received her Ph.D. in Health Policy (Economics Track) from Harvard University. *See* Defs.' Ex. 2 at ¶ 17. She previously served as an Instructor at the University of Chicago, Department of Pediatrics, where her principal research interests focused on the economics of the medical care industry. *Id.* at ¶ 12. She currently serves as Associate Professor of Markets, Public Policy and Law in the Questrom School of Business at Boston University, where she teaches courses on the economics of the medical care industry, and her research interests focus on the economics of the healthcare industry and the markets for pharmaceutical drugs in particular. *Id.* at ¶¶ 12-14.

In addition to being a Professor of Healthcare Economics and serving as a consultant through Greylock McKinnon Associates, Dr. Conti has also published 100 research publications in peer-reviewed health economics and policy journals. *Id.* at ¶ 15. These peer-reviewed publications have focused on topics including

examinations of insurer-related reimbursement and coverage issues, trends in pharmaceuticals use, and pricing of pharmaceuticals. *Id.*

Dr. Conti has testified as an expert before the Senate Finance Committee on causes of ongoing pharmaceuticals shortages. *Id.* She also has testified as an expert at FDA hearings on issues related to pharmaceutical quality. *Id.* Dr. Conti has given invited talks to the United States Government Accountability Office ("GAO"), the Congressional Budgetary Office ("CBO"), the Federal Trade Commission ("FTC"), the National Institutes of Health ("NIH"), and the FDA, among other governmental agencies. *Id.* Moreover, Dr. Conti has served as a consultant to the FDA's Office of Generic Drugs on issues related to drug quality and adequacy of supply. *Id.*

Additionally, she has submitted expert testimony in complex matters involving health economics and allegations related to pharmaceutical sales, pharmaceutical quality, pricing, insurance, and reimbursement and regulation. *Id.* at ¶ 16. Among these matters is *Blue Cross Blue Shield Ass'n v. GlaxoSmithKline LLC,* in which she opined (as she opines here) that adulterated drugs are economically worthless. The *BCBS* court found Dr. Conti's opinions there to be reliable and admissible. 2019 WL 4751883 (E.D. Pa. Sept. 30, 2019).

B. Dr. Conti's Core Opinions and Methodology

Dr. Conti principally opines on the economic value of the at-issue VCDs in this case, and how to calculate the class-wide damages suffered by putative class members for their purchases of these products.

First, [redacted]

[redacted].

Dr. Conti [redacted]

See ECF 2036.

Dr. Conti explains [redacted]

[1] Contrary to Defendants' critique, [redacted]

[redacted]

Indeed, Dr. Conti further explained [redacted]

Next, Dr. Conti [redacted]

[redacted]

Under these circumstances, [redacted]

[redacted]

[2] Other recent cases alleging economically worthless drugs due to cGMP failures have met with success as well. *See, e.g.*, *Faulkner v. Acella Pharms., LLC*, No. 2:22-cv-092 (N.D. Ga.) (after refusing to dismiss complaint and granting leave to amend, preliminary approval granted of $46.5 million settlement on February 7, 2024).

[redacted]

Again, this Court found all of Dr. Conti's opinions, from a methodological and calculations standpoint, to be sufficiently reliable under Rule 702.

[3] As the case law and Defendants' own experts show, [redacted]

C. Dr. Conti's Liability Report

Dr. Conti's liability report, dated February 3, 2023, applies her same methodology and damages modeling as that set forth in her earlier class certification report (which the Court found to be sufficiently reliable and which Dr. Conti incorporated by attaching to and referencing in her Feb. 3, 2023 Report). *See* Defs.' Ex. 3. The only difference is she calculated damages for TPPs nationwide for only a subset of defendants: ZHP, Teva, and Torrent. These are the same Defendants for trial. Dr. Conti also calculated MSP-specific damages based on MSP's own data, which simply provides additional data for consideration at this point.

Defendants gloss over two important points about Dr. Conti's calculations in her liability report. First, at the time she rendered this report, the Court had not yet certified any subclasses. *Compare* Defs.' Ex. 3 (Dr. Conti's Feb. 3, 2023 report), *with* ECF 2261 (Feb. 8, 2023 class certification opinion). Plaintiffs asked Dr. Conti to calculate MSP-specific damages, based on MSP's own data, because it was unclear at the time if the bellwether trial would be a class or individual TPP trial.

Second, because the Court had not yet issued a class certification ruling, the parties did not know which states might be in play for a bellwether trial. The only available guidance at the time was that ZHP, Teva, and Torrent might be the trial defendants. That is why Dr. Conti calculated nationwide TPP damages for purchasers of ZHP's, Teva's, and Torrent's VCDs only.

Importantly, [redacted]

[redacted]

[redacted]

After the Court's certification opinion on February 8, 2023, the Court did not formalize the subclasses for the bellwether trial until April 21, 2023. *See* ECF 2343 (CMO No. 32). And even then those were later refined slightly as the parties met-and-conferred on interpreting the Court's class certification rulings, when Plaintiffs' moved for issuance of class notice, which the Court granted on November 15, 2023. *See, e.g.*, ECF 2535 & ECF 2532-6 (TPP class definitions).

Dr. Conti was deposed a third time about her liability report on July 13, 2023. Defendants never questioned Dr. Conti about her damages calculations by defendant, by state, and by damages theory. *See generally* Defs.' Ex. 6.

[4] Defendants appear to have forgotten they questioned Dr. Conti for ten hours across two separate deposition days. They only attach the first day's deposition transcript to their instant *Daubert* motion. *See* Defs.' Ex. 5.

D. Dr. Conti's Supplemental Liability Report

Because Plaintiffs' original requests for pricing and other data were found to be premature, Retailer Defendants did not produce all pricing and other data for sales of VCDs prior to the Court's class certification decision. After this decision, Plaintiffs re-urged their requests and the Court ordered Retailers to produce these data on April 21, 2023. *See* ECF 2343 (CMO No. 32). The matter required substantial briefing and argument before the Special Master. *See, e.g.*, ECF 2427, 2432, 2440, Ultimately, on August 15, 2023, Retailers were ordered to produce data that included prices paid by TPPs for VCDs. *See* ECF 2471 (SMO No. 83).

These data (the "Pharmacy Defendant Data") were produced over multiple weeks in summer/fall 2023. It is in essence a sample subset of prices. Rather than be accused at trial of 'ignoring' these data (even though it was just produced, over heavy defense resistance), Plaintiffs proposed Dr. Conti submit a supplemental liability report addressing the existence of the newly produced Pharmacy Defendant Data, albeit substantially less complete than the IQVIA data.

The Court allowed it, and Plaintiffs tendered Dr. Conti's supplemental liability report on December 1, 2023. [redacted]

[redacted]

In other words, [redacted]

[redacted]

Dr. Conti discussed in her Supplemental Report and testified [redacted]

[redacted]

[redacted]

Plaintiffs simply asked Dr. Conti to consider the Pharmacy Defendant Data, and to discuss its probative value and any limitations to it, because counsel judged this to be appropriate under the circumstances. [redacted]

[redacted]

IV. ARGUMENT

A. Another Court in This Circuit Has Already Found Dr. Conti Qualified and Her Opinions Reliable in a Case Nearly Identical to This One

As this Court rightly recognized at class certification (*see* ECF 2261 at 88-89), another court in this circuit (*BCBS*) has already analyzed Dr. Conti's qualifications and methodology (nearly identical to that she employs here); found her to be qualified; found her methodology reliable; and, therefore, found her opinions admissible. *BCBS,* 2019 WL 4751883, at *8-9.

In *BCBS*, thirty-eight different TPPs sought to recoup their reimbursements for drugs there were adulterated due to cGMP failures. *Id.* at *1. The *BCBS* plaintiffs, as Plaintiffs here, argued that the adulterated drugs were economically worthless and they would not (and could not) have been purchased had the manufacturer disclosed the cGMP deficiencies and adulteration. *Id.* The *BCBS* plaintiffs relied on Dr. Conti's economic analysis that "there can be no legitimate supply curve to establish economic value" for drugs made in a non-cGMP compliant manner "because the FDCA prohibits the sale of adulterated drugs." *Id.* at *2.

The *BCBS* defendants sought to exclude Dr. Conti's opinions for many of the same reasons Defendants argued at class certification, and reargue now. For instance, the *BCBS* defendants argued that Dr. Conti impermissibly based her opinion on a legal interpretation, that her model was not based on reliable economic methodology, and that her calculations were flawed for not assessing other data points such

potential offsets or rebates. *Id.* at *8. Judge Sánchez thoughtfully analyzed and rejected each challenge, *see id.* at *7-8, and ultimately found that the defendant's critiques went to credibility, not admissibility, *id.* at *8.

At the class certification stage here, Defendants attacked Judge Sánchez by accusing him of having "abdicated" his judicial obligations and not conducting a "serious analysis." ECF 2040-1 at *8. Defendants are equally blunt, and equally unpersuasive, this time around, too. They declare *BCBS* was erroneously decided (*see* Defs.' Mem. at 18), without any citation to intervening authority. The intervening authority (including this Court's own reasoned analysis) actually sides with Judge Sánchez's conclusion. Specifically, the Eleventh Circuit found in *Debernardis v. IQ Formulations, Inc.*, that adulteration of dietary supplements resulting in their having been illegally sold was a material defect resulting in economic worthlessness. 942 F.3d 1076, 1088 (11th Cir. 2019). This Court has already agreed with that analysis. ECF 775 at 20 ("[T]his court is persuaded by *Debernardis* …."); *accord Yachera v. Westminster Pharms., LLC*, 477 F. Supp. 3d 1251, 1264 (M.D. Fla. 2020) (plaintiffs allowed to proceed on worthless drug theory against manufacturer where drug was adulterated because it did not contain amount of API as stated on the label).

Defendants also bolt-on their fallacious summary judgment argument that the new amendment to Rule 702 changed the calculus on this Court's consideration of

Dr. Conti's opinions (but not their own experts' opinions). *See id*. But as noted *supra* Part II, the new amendment to Rule 702 explicitly did *not* impose any new edict or procedures. To the extent any further analysis of the application of Dr. Conti's methodology is called for, this Court did already find the methodology to be sufficiently reliable and reliably applied—and the discovery since then only re-affirms that Dr. Conti applied her methodology in a reliable manner.

B. Dr. Conti is Qualified to Offer Her Opinions

Defendants do not challenge Dr. Conti's qualifications in any respect.

C. Dr. Conti's Opinions Are Reliable

Defendants' purported reliability-related arguments range from disagreeing with Dr. Conti's conclusion that [redacted] None of these is a legitimate basis to challenge the reliability and application of Dr. Conti's methodology—not to mention, this Court already rejected these nearly identical arguments at class certification.

Plaintiffs respond to each of Defendants' misguided attacks below. But an

overarching consideration is that the standard for reliability is lower than the merits standard for determining whether the expert is correct or whether a defendant ultimately is liable. *Oddi v. Ford Motor Co.*, 234 F.3d 136, 155-56 (3d Cir. 2000). So long as an expert's testimony rests upon good grounds, based on what is known, "it should be tested by the adversary process -- competing expert testimony and active cross-examination -- rather than excluded from jurors' scrutiny." *Id.*

This is especially true in cases involving experts in the field of economics. Because the discipline of economics requires "the use of professional judgment" the expert testimony of an economist is less likely to be excluded because challenges may ultimately be viewed as matters where "reasonable experts may differ." *In re Mushroom Direct Purchaser Antitrust Litig.*, 2015 WL 5767415, at *6 (E.D. Pa. July 29, 2015); *see, e.g.*, *In re Avandia Mktg., Sales Pracs. & Prod. Liab. Litig.*, 804 F.3d 633, 640 (3d Cir. 2015) ("The TPPs' damages do not depend on the effectiveness of the Avandia that they purchased, but rather on the inflationary effect that [defendant's] allegedly fraudulent behavior had on the price of Avandia.").

1. Defendants Incorrectly Focus on Dr. Conti's Conclusions, Not Her Methodology

The centerpiece of Defendants' *Daubert* motion is their disagreement with Dr. Conti's conclusion that at-issue VCDs were economically worthless. Defendants lead with this on line one of page one of their motion. *See, e.g.*, Defs.' Mem. at 1. Putting aside the Court's rejection of this exact *Daubert* argument at class

certification (not to mention agreeing with Dr. Conti's methodology at the motion to dismiss stage (*see* ECF 775, at 20 ("This Court finds that contaminated drugs are economically worthless at the point of sale ….")))), Defendants once again cite precious little for their unreasonable disagreement. The best they muster is Dr. Conti's opinions, well-informed by her 20+ years of healthcare economics and based on facts of record, is contrary to "common sense." *Id.*

Mere disagreement with an expert's conclusions, rather than her methodology, is not an appropriate basis for challenge under *Daubert*. The Court's *Daubert* analysis must be driven by the methodology and expertise employed, and not the ultimate conclusions upon which the expert arrives. *Jama v. Esmor Corr. Servs., Inc.*, 2007 WL 1847385, at *27 (D.N.J. June 25, 2007) ("The Supreme Court in *Daubert* has stated that the focus of the inquiry should be solely on principles and methodology, not on the conclusions that they generate."); *see, e.g.*, *Lambeth Magneti Structures, LLC v. Seagate Tech. (US) Holdings, Inc.*, 2022 WL 864170, at *1 (W.D. Pa. Mar. 22, 2022) ("disagreement with [expert's formulation] does not render her opinion inadmissible under *Daubert*. Rather, such arguments properly go to the weight of the evidence."). This is unchanged by the recent amendment.

As discussed *supra* Part III.B, Dr. Conti properly applied a reliable methodology to the facts of this case. Her opinions align with the theories of liability in this case. Defendants' objection to her conclusions does not implicate the

reliability, and thus the admissibility, of her opinions.

To the extent Defendants argue Dr. Conti's damages modeling is unreliable because [redacted] These are exactly the types of assumptions that *damages* experts routinely must and do make. *See, e.g.*, *Rhoads Indus., Inc. v. Shoreline Found., Inc.*, 2021 WL 2778562, at *30 (E.D. Pa. July 2, 2021) ("In fact, all damages expert opinions are dependent . . . on the assumption that liability has been proven.") (internal quotation marks and citation omitted).

2. Dr. Conti Incorporates Therapeutic Value in Her Analysis

Defendants also argue (again) that Dr. Conti's methodology is unreliable because she [redacted]. *Id.*

Again, this aligns with the facts in this case, [redacted] This Court has recognized that the economic harm class members suffered occurred at the point of sale, which is what Dr. Conti calculates. *See* D.E. 775 at 19-20 ("contaminated drugs, even if medically efficacious for their purpose, cannot create a benefit of the bargain because the contaminants, and their dangerous effects, were never bargained for").

Given such, as Defendants' own experts concede, [redacted] And ultimately, whether "Plaintiffs' damages calculation [by Dr. Conti] is improper because Plaintiffs should have discounted any therapeutic value they received from the noncompliant drugs [] is necessarily a credibility dispute between the parties' experts." *BCBS*, 417 F. Supp. 3d at 557.

3. Dr. Conti's Methodology Incorporates the Real World of Prescription Pharmaceutical Sales

Related to Defendants' conflation of "therapeutic value" and "economic value" is their equally specious contention that Dr. Conti [redacted] Indeed, the Court has already excluded Defendants' expert (Dr. Punam Keller) who attempted to offer this exact opinion, describing it as Dr. Keller's unsupported "say-so." ECF 2261, at 77-78.

First, unlike Defendants and some of their experts, Dr. Conti's methodology incorporates and relies upon [redacted]

[redacted]

Further still, Dr. Conti's analysis of [redacted]

Defendants' insistence that Dr. Conti should have put all of the real-world facts and data aside [redacted]

[redacted]. This argument is so far removed from fitting the facts of this case that it should be precluded on Plaintiffs' MIL to avoid confusing the jury and wasting trial time debating something that could not happen. At worst it presents a fact question. An expert is permitted to base their opinion on a particular version of disputed facts, and the weight to be accorded to that opinion is for the jury. *Walker v. Gordon*, 46 F. App'x 691, 696 (3d Cir. 2002).

Defendants' newly concocted suggestion that contaminated valsartan *sold in other countries* might have had economic value (*see* Defs.' Mem. at 20) bears special call out. This litigation is about the FDA-mandated, product-wide recalls for *all* of Defendants' VCDS in *this* country. It is not about hypothetical purchases of VCDs in other countries, with different regulatory regimes.[5] The fact that the FDA declared ZHP's valsartan API adulterated due to the nitrosamine contamination, and all Defendants removed all of their VCDs from the market in the summer 2018, means exactly what Dr. Conti, Retailer Defendants', Wholesaler Defendants', and even Manufacturer Defendants' own witnesses all say: there was no market in the United States for Defendants' contaminated, adulterated, or misbranded VCDs. [redacted]

[5] Long ago, Plaintiffs were substantially denied 'foreign discovery' about VCDs. If Defendants intend to open the door to VCD sales abroad, Plaintiffs expressly reserve the right to seek preclusion and/or expedited discovery.

[redacted]

Again, the undisputed evidence underscores this, as the demand curve for Defendants' VCDs precipitously dropped to zero after the recalls. *See supra* n.2.

4. Offsets Are Irrelevant to Reliability

Once again, Defendants trundle out their previously rejected *Daubert* argument that Dr. Conti's methodology is unreliable because it does not exhaustively account for [redacted]

[redacted] As before at class certification, Defendants' unsupported arguments are speculative and substantively inaccurate. Even if they were not, they go to the weigh or credibility of Dr. Conti's opinions, not reliability. Defendants' attack fails (again) for at least three reasons.

First, as a general matter, and as an affirmative defense on which Defendants bear the burden of proof, potential offsets neither preclude class certification nor render an expert's damages calculations unreliable. *See, e.g.*, *Stuart v. Global Tel*Link Corp.*, 956 F.3d 555, 561 (8th Cir. 2020); *In re Linerboard Antitrust Litig.*, 305 F.3d 145, 162 (3d Cir. 2002). This is because such adjustments go to the extent, not the fact, of injury. Denying class certification based on a finding of individualized damages would "amount[] to an abuse of discretion." *Neale v. Volvo*

Cars of N. Am., LLC, 794 F.3d 353, 375 (3d Cir. 2015); *see also In re Novo Nordisk Sec. Litig.*, 2020 WL 502176, at *9 (D.N.J. Jan. 31, 2020).

Second, Dr. Conti does not 'ignore' Medicare monies. *See* Defs.' Mem. at 3, 22. [redacted]

Third, Medicare monies are plainly speculative and barred by the collateral source doctrine. Plaintiffs thoroughly set this out in their *Daubert* motion to preclude Defendants' expert Wayne Gibson (*see* ECF 2631) and in Plaintiffs' omnibus motion *in limine* (*see* ECF 2648). For efficiency's sake, Plaintiffs simply incorporate their law and argument in those filings here, but highlight that the collateral source rules provide that, "a tortfeasor should be held accountable for the wrong done and should not benefit from the fact that the victim later escapes some of the consequences of the harm." *In re HIV Antitrust Litig.*, 2023 WL 3603732, at *2 (N.D. Cal. May 23, 2023) (granting motion *in limine* precluding defendants, including Teva, from arguing to jury that Medicare monies are offsets); *In re Zetia (Ezetimibe) Antitrust Litigation*, 2023 WL 3064462 (E.D. Va. Apr. 18, 2023) (precluding evidence and argument to the jury, including opinions of Dr. Laura Stiroh, one of Defendants' experts here, about Medicare monies under the collateral source rule and that it would only mislead and confuse the jury); *see, e.g.*, *Craig v.*

Y & Y Snacks, Inc., 721 F.2d 77, 83 (3d Cir. 1983) (unemployment benefits received by plaintiff should not reduce plaintiff's recovery); *Titchnell v. United States*, 681 F.2d 165 (3d Cir. 1982) (Medicare payments subject to collateral source rule); *see also Page v. State Farm Life Ins. Co.*, 584 F. Supp. 3d 200 (W.D. Tex. Feb. 10, 2022) (post-verdict class damages can be adjusted if jury finds any offset appropriate).

Further, a defendant bears the burden of demonstrating an offset to damages. *See, e.g.*, *Hilburn v. N.J. Dep't of Corr.*, 2012 WL 3133890, at *27 (D.N.J. July 31, 2012) ("The defendant typically bears the burden of proving that an offset to damages is appropriate."). In that regard, Defendants have utterly failed to do so. They have not quantified or estimated the amount of purported 'offsets' they say should apply. [redacted]

Finally, even if Defendants were entitled to these "offsets" (they are not); if they had carried their burden to demonstrate their existence (they have not); and if offsets were for the jury (and they are not; at best they are for the Court post-verdict, *see, e.g.*, *In re HIV Antitrust Litig.*, 2023 WL 3603732 at *2), [redacted]

[redacted]

But of course, Defendants did not provide reliable amounts to input.

D. Dr. Conti Relies on "Sufficient Facts or Data"

Defendants' new attack on Dr. Conti's continued use of IQVIA data (which she used at class certification as well) boils down to this: when she uses two different data sets (IQVIA data and Pharmacy Defendant Data), she gets different results. Defs.' Mem. at 2-3, 6, 8. The mathematical truism that different inputs yield different results when run through the same formula should hardly come as a surprise; it certainly does not implicate the admissibility of Dr. Conti's opinions. As Dr. Conti explained in both her supplemental report and at her recent deposition and also discussed herein *supra*, [redacted]

As discussed above, [redacted]

[redacted]

[redacted]

At bottom, nothing has changed since this Court found Dr. Conti's class damages opinions, based on IQVIA data, reliable. Dr. Conti considered the Pharmacy Defendant Data (and applied her same reliable methodology to it), but reaches the same conclusion that IQVIA is the most reliable and most robust data for providing a "reasonable estimate" of class damages. *Rossi v. Standard Roofing, Inc.,* 156 F.3d 452, 484 (3d. Cir. 1998). Dr. Conti's consideration of all available data does not result in her opinions somehow lacking sufficient data. To the contrary, Dr. Conti uses the best data available for presenting the relevant pharmaceutical sales and pricing. Whether one data set is 'better' than the other goes to weight, not admissibility. *See, e.g.*, *10x Genomics, Inc. v. NanoString Techs., Inc.*, 2023 WL 5805585, at *12 (D. Del. Sept. 7, 2023) (whether using different data sets might result in different calculations goes to weight, not admissibility); *In re Proton-Pump Inhibitor Prods. Liab. Litig.*, 2022 WL 18999830, at *33 (D.N.J. July 5, 2022) (weight given to different studies is province of jury); *In re J&J Talcum Powder*

Prods. Mktg., Sales Pracs. & Prods. Liab. Litig., 509 F. Supp. 3d 116, 192 (D.N.J. 2020) (experts' disagreement over which data should be evaluated does not render opinion unreliable).

Defendants' insinuation that [redacted] ts

[redacted]

[8] *See, e.g.*, *In re Nat'l Prescription Opiate Litig.*, 2019 WL 3934470, at *10 (N.D. Ohio Aug. 20, 2019) ("IQVIA's data is the best third-party evidence available to show the path the Manufacturers' opioid products took"); *UCB, Inc. v. Teva Pharms. USA, Inc.*, 2015 WL 11199058, at *6-7 (N.D. GA. Mar. 18, 2015) ("The IMS Health data [now known as IQVIA data] [the expert] used in his analysis is considered reliable and accurate and is commonly used for auditing purposes."); *In re Zyprexa Prods. Liab. Litig.*, 2008 WL 2696916, at *91-96 (E.D.N.Y. July 2, 2008) ("Both data sources originated from IMS Health [now known as IQVIA] and are frequently used in scholarly analyses of the pharmaceutical industry"); *In re Cardizem CD Antitrust Litig.,* 218 F.R.D. 508, 526 (E.D. Mich. 2003) (approving use of IMS data (now known as IQVIA data)).

[redacted] The retailer sample of data that was recently produced has been included in the analysis, providing more information for the benefit of the jury.

E. Dr. Conti's Opinions "Fit" the Facts of This Case

"Fit" is a relatively low bar. It simply means the expert's testimony must assist the trier of fact (i.e., be helpful), and be related to the theories of liability in the case (i.e., relevant). *See, e.g.*, *Comcast Corp. v. Behrend*, 569 U.S. 27, 37-38 (2013); *United States v. Ford*, 481 F.3d 215, 219-20 (3d Cir. 2007) (threshold for analyzing fit is "not high."). This Court already found that Dr. Conti's opinions fit, *viz.*, it would be helpful and relevant to the jury. *See* ECF 2261 at 86-89.

Nothing has changed since. The only new 'fit' argument that Defendants muster are recycled from their summary judgment motion: a purported mis-match between the subclass definitions and where "point of sale" for VCDs occurred. Defs.' Mem. at 15. This argument fails. ECF 2343 (CMO No. 32) at 1; *see* ECF 2262 & Table 4. Dr. Conti's damages model fits because [redacted]

[redacted] Case law also comports with the record in this case. *See, e.g.*, *Caremark LLC v. AIDS Healthcare Found*., 2022 WL 4267791, at *3 (D. Ariz. Sept. 15, 2022);[11] *Stafford v. Rite Aid Corp*, 2020 WL 905606, at*1 (S.D. Cal. Feb. 25, 2020).[12] Even if none of this were the case (and it is), Defendants' position really is just another facet of their offsets argument (i.e., the amount paid by a TPP at point of sale might not reflect the ultimate net amount paid due to post-transaction adjustments, etc.). As indicated above, such arguments do not implicate the admissibility of Dr. Conti's opinions.

V. CONCLUSION

For the foregoing reasons, Defendants' *Daubert* motion should be denied.

[redacted]

[11] "This process confirms the prescribed product is covered by the customer's health plan *and advises the pharmacy the reimbursement rate at the point of service for the drug*….." (Emphasis added).

[12] "The process by which financial responsibility between third-party payors and plan participants is determined is called 'adjudication'. ….The contracts specify Rite Aid's obligations to the TPP or PBM when submitting claims for prescription coverage *at the point of sale, as well as the amount Rite Aid will receive as payment when filling prescriptions.*" (Emphasis added).

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on this 26th day of February, 2024, I caused a true and correct copy of the foregoing to be filed and served upon all counsel of record by operation of the Court's CM/ECF system. In addition, I certify that unredacted versions of the foregoing will be served contemporaneously upon liaison counsel for Defendants as well as the Court.

/s/ David J. Stanoch
David J. Stanoch